November 16, 2021

Amco International Manufacturing & Design, Inc.
Alexander Henderson
Technical Consultant
377 Zane Ct.
Elizabeth, Colorado 80107

Re: K072596
Trade/Device Name: Life+cel Or Lifecel Battery Pack, Model 5l500
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated external defibrillator system
Regulatory Class: Class III
Product Code: MKJ

Dear Alexander Henderson:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 24, 2008. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code MKJ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Shih, Office of Cardiovascular Devices, 301-796-5813, Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2008

Amco International Manufacturing & Design, Inc.
c/o Mr. Alexander Henderson
Phoenix Technology
377 Zane Court
Elizabeth, CO 80107

Re: K072596
Trade Name: 5L500 life+cel™ or lifecel™ Battery Pack
Regulation Number/Name: unclassified
Regulatory Class: III (three)
Product Code: MOY
Dated: January 8, 2008
Received: January 11, 2008

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PHOENIX TECHNOLOGY

INDICATIONS FOR USE STATEMENT

510(K) Number: K072596

Device Name: 5L500 life+cel or lifecel Battery Pack

Indications for Use:

The 5L500 Lithium life+cel or lifecel is a replacement battery pack for the Medtronic LifePak 500 AED.

Since non-rechargeable batteries and battery packs are "device specific", and are designed to operate and fit into the equipment for which they were manufactured, only qualified personnel should evaluate, test, charge, or install these devices.

This battery is shipped only to customers who request a replacement battery for a particular device or to replace a competitor's replacement battery. Biomedical equipment service professionals, EMT's, etc. therefore know that the intended use is as a replacement battery.

The replacement battery pack in this submission, Amco Part Number 5L500, is to be provided by prescription only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072596

377 Zane Court • Elizabeth, Colorado USA 80107
Telephone: 303-646-3715 • Email: alex_henderson@phoenixsolutions.org

JAN 24 2008

PHOENIX TECHNOLOGY

510(k) Summary – K072596

Replacement Battery Pack 5L500

Submitter: Amco International Manufacturing & Design, Inc.
Attn: Mr. Adam Milewski
69-81 108th Street, Suite 6G
Forest Hills, New York 11375

Contact Person: Alexander B. Henderson
Phoenix Technology
377 Zane Court,
Elizabeth, CO 80107
Tel: 303-646-3715
Email: alex_henderson@phoenixsolutions.org

Date Prepared: September 10, 2007

Device Name:

Trade/Proprietary Name:	life+cel™ or lifecel™ Battery Pack
Common/Generic Name:	Box Battery
Classification Name:	Box, Battery, Non-Rechargeable

Classification: **Cardiovascular Panel**

		Class
21CFR 870.1025	Arrhythmia Detector and Alarm	II
21CFR 870.1110	Blood Pressure Computer	II
21CFR 870.1130	Systems, Measurement, Blood Pressure, Non-Invasive	II
21CFR 870.2300	Monitor, Cardiac (Including Cardio tachometer & Rate Alarm)	II
21CFR 870.2340	Electrocardiograph	II
No Regulatory Reference	Rechargeable Batteries for Class III Devices	III

Legally Marketed Predicate Devices:

This submission compares the specifications and functionality of AMCO Lithium 5L500 life+cel or lifecel battery packs with those of similar devices that were included as part of the following original predicate equipment and submissions:

The AMCO **5L500** life+cel™ is the same as that used in the Medtronic Emergency Response System LifePak 500 AED cleared under 510(k) notif ication K052057.

Description:

The AMCO 5L500 life+cel™ Non-rechargeable battery pack is utilized as a primary direct current (d-c) power source or as a standby or backup d-c power source for portable as well as stationary medical equipment.

Statement of Intended Use:

To power the functions of various devices for which the batteries or battery packs are intended.

Comparison of Technological Characteristics

The design components and functionality of the AMCO Lithium 5L500 life+cel or lifecel battery packs listed are similar to those of their predicate devices. All these devices provide a means of supplying electrical power through chemical reaction. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of c urrent used by the device into which they are installed. The performance and life span of these batteries depends on operating conditions of temperature, current drain, and the charge/discharge method (if applicable). These parameters are taken into accoun t in designing such batteries. The goal is to develop battery packs that maintain capacity for as high and as long as possible. Typical cell chemistries are Lithium Sulfur Dioxide, Sealed - Lead Acid (SLA), Nickel-Cadmium (NiCd), and Nickel-Metal Hydride (NiMH).

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BATTERY PACK TESTING – GENERAL PROTOCOL

INCOMING INSPECTION

All cells are inspected for correct specification, visible damage, and randomly voltage tested prior to acceptance. The lot numbers are recorded for tracking purposes should any fail during final assembly and inspection activities. Cases are also inspected for form, fit, function, and cosmetics.

CADEX TESTING

Voltage and capacity of non-rechargeable battery cells and core packs are tested using a Cadex Electronics Battery Analyzer Model C7400ER (Extended Range) in the "Auto Mode" This exercises the batteries in order to identify performance characteristics by running them through a full discharge cycle. Tests typically take 12 hours for each bat tery pack. Non-Rechargeable packs are tested to depletion on a random lot sample basis.

All battery chemistries can be tested using custom test parameters, depending on Quality Control and customer requirements. This allows for various C -Rates, delta V (ΔV), and volts-per-cell to be entered into the test protocol through the Cadex Battery Sho p Software utility (Reference Cadex Test Report Examples – Exhibit A).

Target capacity is the percentage of the battery capacity compared to nominal capacity and serves as a threshold. This threshold, or target capacity, can be set to any desired range (9 0 - 95% is typical).

Target capacity is a pass/fail mark and our batteries must meet or exceed a required threshold of 90%, or higher, prior to final Quality Control inspection. Any samples that do not meet the criteria are rejected, and subsequently, the entire lot is tested in this manner.

Battery packs are not shipped fully charged (except non -rechargeable Lithium types). There are specific DOT, FAA, and EPA regulations and guidelines that address these concerns.

VOLTAGE TESTING – Completed Packs

All Battery Packs are tested 100% for correct voltage / polarity prior to shipment. Those devices that fail are rejected and quarantined.

DEFIBRILLATOR TESTING

Independent testing (Beta Tests), as well as random tests on finished packs, are performed using NETECH Model Delta 2000 Defibrillator Analyzers to insure that they meet the expected number of shocks as specified by the OEM's.

BATTERY PACK TESTING (continued)

SAFETY and PERFORMANCE

Safety and performance testing of battery packs are performed to ensure that these devices meet all functional requirements and performance specifications.

In comparison analysis, OEM Battery Packs set the benchmark. Replacement devices must meet or exceed these benchmark results consistently.

Concerns that are addressed during bench test comparison analysis are:

- **Life cycle**

  The replacement battery must provide as many or more charge and discharge cycles as the original. This is an ongoing process and is not part of the standard QC final inspection protocol. Shelf life, on the other hand, is based on the original cell manufacturer's specification sheets and Certificates of Conformance.

- **Temperature**

  The replacement battery must function correctly over the same temperature range as compared to the original. Testing is done at 0, 25, and 40°C (32, 77, and 104°F respectively).

- **Mechanical & Electrical Component Integrity**

  Normal testing would involve drop tests from a predetermined height, usually 2 -3 feet, onto a hard, uniform surface. Battery packs are inspected for case cracks, cell separation, and electrical/electronic component damage. Root cause analysis is performed should any damage occur.

  - If there is no visible damage, the battery is tested for form, fit, and function.
  - Active Safety devices are inspected and tested before use and after installation.

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